UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY
NEWARK DIVISION

VARIOUS PLAINTIFFS,

v.

ASTRAZENECA PHARMACEUTICALS LP; and ASTRAZENECA LP,

Defendants.

Civil Action No.: 16-5143(Steven Goodstein)
Civil Action No.: 17-196 (Gary Savage)
Civil Action No.: 17-201 (Cheryl Aubrey)
Civil Action No.: 17-203 (Zenobia Toney)
Civil Action No.: 17-206 (Susan Stewart)
Civil Action No.: 17-208 (Dale Scott)
Civil Action No.: 17-212 (Kimberly Lee)
Civil Action No: 17-215 (Deborah Wilkerson)
Civil Action No: 17-217 (Kelly Gutierrez)
Civil Action No: 17-219 (John Hudson, as Anticipated Personal Representative for the Estate of Helena Hudson)
Civil Action No: 17-761 (Naomi Massengill)
Civil Action No: 17-194 (Jon Adkins)
Civil Action No: 17-198 (Anita Pierre)
Civil Action No: 17-202 (Diane Gilyard)
Civil Action No: 17-204 (Vicky Watkins)
Civil Action No: 17-207 (Clara Graves)
Civil Action No: 17-211 (Tony Carruthers)
Civil Action No: 17-213 (Joseph Wilburn)
Civil Action No: 17-216 (Laura Layton)
Civil Action No: 17-218 (Misty Hawkins)
Civil Action No: 17-500 (Freddie Lloyd)

JOINT STATUS REPORT AND PROPOSED INITIAL DISCOVERY PLAN

Pursuant to Fed. R. Civ. P. 26(f), initial conferences of the parties subject to the above-referenced cause numbers were held on February 22, 2017 and March 15, 2017 with counsel for all parties.

The following initial issues and alternative discovery plans were discussed:

1. Set forth the name of each attorney appearing, the firm name, address and telephone number and facsimile number of each, designating the party represented.

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2. Set forth a brief description of the case, including the causes of action and defenses asserted:

Plaintiffs' description of the cases and causes of action:

The actions before the Court allege that as a result of the ingestion of Nexium, plaintiffs suffered and were diagnosed with kidney injuries including acute interstitial nephritis ("AIN"), acute kidney injury ("AKI"), chronic kidney disease ("CKD"), and renal failure, also known as end-stage renal disease ("ESRD"). Plaintiffs claim that Defendants failed to adequately warn that the ingestion of these prescription and/or over-the- counter drugs could cause irreparable harm to the kidneys, defectively designed and formulated Nexium, and breached the express warranties made about the drugs' safety.

By way of background, Nexium is in a class of medications called Proton Pump Inhibitors ("PPIs"). PPIs are a group of drugs intended to act as hydrogen potassium ATPase ("H+/K+ ATPase") enzyme inhibitor to block the production of gastric acid. PPIs have been widely promoted by the Defendants as an effective drug to be used for the prevention and treatment of gastric acid related conditions including, but not limited to, the following:

- Gastroesophageal Reflux Disease ("GERD");
- NSAID-Associated Gastric Ulcers;
- Duodenal Ulcer Recurrence;
- Pathological Hypersecretory Conditions (i.e. Zollinger-Ellison Syndrome); and
- "Frequent" Heartburn (two or more days a week).

Since their introduction to market in 1989, there have been several scientific studies demonstrating an association between PPI use and the injuries described above, the most recent having been published as late as December of 2016.

In December of 2014, the FDA required that the labels of prescription PPIs be updated to read, in the relevant part:

> Acute interstitial nephritis has been observed in patients taking PPIs including [Brand]. Acute interstitial nephritis may occur at any point during PPI therapy and is generally attributed to an idiopathic hypersensitivity reaction. Discontinue [Brand] if acute interstitial nephritis develops. 1

PPI-induced AIN is difficult to diagnose with patients most commonly complaining of non-specific symptoms such as fatigue, nausea, and weakness. Recent findings published

1 While the term "interstitial nephritis" did appear in the Postmarketing Experience section of the October 2006 Nexium label, it was characterized as being "rarely" reported and was not added to the Warnings and Precautions section of the label until 2014.

in the *Journal of Nephrology* by Dennis Moledina and Mark Perazella of the Yale University School of Medicine suggest that the development of and failure to treat AIN could lead to CKD and ESRD, which requires dialysis or kidney transplant to manage. Evidence from these studies incriminates all commercially-available PPIs, thereby suggesting a class effect.

CKD describes a slow and progressive decline in kidney function where wastes can build to high levels in the blood resulting in numerous, serious complications ranging from nerve damage and heart disease to kidney failure and death. Prompt diagnosis and rapid withdrawal of the offending agent are vital in order to preserve kidney function. While AIN can be treated completely, once it has progressed to CKD it is incurable and can only be managed. This factor, combined with the lack of numerous early-onset symptoms, highlights the need for screening of at-risk individuals. In January of 2016, a study published in the *Journal of the American Medical Association* found that PPI use was independently associated with a 20-50% higher risk of CKD. To date, over-the-counter PPIs lack detailed risk information for AIN while prescription and over-the-counter PPIs lack detailed risk information for AKI, CKD, or ESRD.

Claims Asserted

Many of the complaints in the Nexium cases assert similar causes of action, including: design defect, failure to warn, breach of express warranty, punitive damages, and loss of consortium (as applicable). All of the complaints make very similar factual allegations and, thus, any necessary discovery will arise from common questions of fact.

Specifically, plaintiffs bring the following claims:

1. Product Liability – Defective Design

The design and formulation of Nexium was defective in that the drug was not safe for its intended purpose and that its risks exceeded its benefits. Sold in its defective condition, Nexium was unreasonably dangerous for its intended use as it subjected Plaintiffs to serious and permanent injuries. Nexium was more dangerous than an ordinary consumer would expect and more dangerous than other alternative treatments.

For example, such safer alternative treatments include but are not limited to the use of over-the-counter calcium carbonate remedies tablets that have been available since the 1930s, such as Maalox and Tums, and/or the use of histamine H2-receptor antagonists (also known as H2 blockers) that were developed in the late 1960s. H2 blockers act to prevent the production of stomach acid, and work more quickly than PPI. Examples of H2 blockers are Zantac, Pepcid, and Tagamet.

The design and formulation defects existed before it left the control of the manufacturers. The drug was inadequately tested before being released onto the market, and was then

inadequately labeled for the full extent of its risks and side effects. Feasible alternatives (such as that of H2 receptor antagonists) to the PPI's defective design and formulation could have prevented or reduced the risk of injuries without impairing the function of the product.

2. Product Liability – Failure to Warn

Nexium was defective and unreasonably dangerous before entering the consumer market. The drug's warnings were insufficient to alert physicians and consumers to its dangerous renal risk and side effects. As noted, it was not until December of 2014 that AIN was mentioned in Defendants' Nexium warnings. Even today, there is no warning for the more serious renal injuries of AKI, CKD, or ESRD.

In short, the Defendants failed to provide adequate post-marketing warnings and instructions to consumers, as the Defendants knew or should have known the serious risk of injury associated with the use of the drug, especially given the plethora of studies available supporting such causation.

The Defendants, as manufacturers and distributors, are held to the level of knowledge of experts. They failed to properly warn physicians of increased risks of injuries, and as such, the plaintiffs reasonably relied upon the skill, knowledge, and judgment of Defendants. Each of the plaintiffs used the drug as intended, and had they received adequate warnings regarding the associated risks, each plaintiff would not have used the drug and/or chosen a different treatment.

3. Breach of Express Warranty

The Defendants expressly represented Nexium as safe and fit for intended purposes, that I did not produce dangerous side effects related to renal injury, and was adequately tested. *See, e.g.*, "Heartburn Relief With NEXIUM® (esomeprazole magnesium)", *available at* https://www.purplepill.com/heartburn-relief.html (stating "1 NEXIUM pill a day provides 24-hour relief from persistent heartburn cause by acid reflux disease."). *See also* "NEXIUM Side Effects", archived March 5, 2013 version, *available at* https://web.archive.org/web/20130305232228/http://www.purplepill.com/taking-nexium/side-effects.aspx? (outlining diarrhea and bone fracture risks, but failing to outline any other significant side effects).

Nexium, however, did not conform to these express representations put forth by the Defendants because they carried significant additional renal side effects, as discussed above. At the time of making express warranties, the Defendants knew or reasonably should have known that these representations and warranties were false, misleading, and untrue.

4. Punitive Damages Allegations

The wrongs done by Defendants were aggravated by malice, fraud and negligent disregard for the rights of others, the public, and plaintiffs. Given the wealth of studies available, Defendants were subjectively aware of the risks involved but proceeded to disregard the rights, safety, and welfare of others despite the known renal risks.

Acting for the purpose of enhancing profits, Defendants knowingly failed to remedy the known defects and warn the public. The Defendants willfully proceeded to manufacture, sell, distribute and market Nexium despite the knowledge of safety risks to consumers. Their conduct warrants an award of exemplary and punitive damages to plaintiffs.

Defendants' description of the case and defenses:

Defendants deny all of Plaintiffs' allegations as set forth above and in Plaintiffs' Complaints and contend AstraZeneca is not responsible for the damages alleged.

By way of background, Nexium®, first approved as safe and effective by FDA in 2001, is a branded prescription product of esomeprazole magnesium and is marketed and sold in the United States by AstraZeneca. Nexium® is a proton pump inhibitor ("PPI"), which works by reducing acid in the stomach. Physicians prescribe PPIs like Nexium® as the gold-standard treatment to reduce the risk of stomach ulcers in patients taking non-steroidal anti-inflammatory drugs, to treat patients with helicobacter pylori stomach infections (along with antibiotics) and for the long-term treatment of certain hypersecretory conditions. Nexium® is also used to treat the symptoms of GERD (gastroesophageal reflux disease) and may be prescribed to heal acid-related damage to the lining of the esophagus.

As an initial matter, all but one[2] of the cases ("Resident Plaintiff/s") subject to the Initial Status Conference involve initial jurisdictional and other potentially dispositive issues ("Non-Resident Plaintiffs").[3] As set forth in AstraZeneca's March 9, 2017 letter to the Court and in the proposed schedule below, AstraZeneca intends to file initial motions related to lack of personal jurisdiction, venue and other dispositive pleading deficiencies.

2 *Goodstein v. AstraZeneca et al.,* Civil Action No: 16-5143 (CCC).

3 The Non-Resident Plaintiffs all allege that they are residents and citizens of states other than New Jersey. The Non-Resident Plaintiffs' residency allegations, lack of allegations of injury in New Jersey, and lack of assertion that their injuries arise from any alleged activities of AstraZeneca in New Jersey do not subject AstraZeneca to specific personal jurisdiction in New Jersey. The Non-Resident Plaintiffs also cannot subject AstraZeneca to general personal jurisdiction in New Jersey because neither AstraZeneca Pharmaceuticals LP nor AstraZeneca LP, two separate Delaware entities, can reasonably be considered "at home" in New Jersey.

While dismissal of the Non-Resident Plaintiffs for lack of personal jurisdiction is appropriate, in the alternative, and at a minimum, the Non-Resident Plaintiffs' claims should be transferred to the appropriate home district under 28 U.S.C. § 1404(a). The Non-Resident Plaintiffs are residents and citizens of states other than New Jersey and indispensable, non-party trial witnesses such as the Non-Resident Plaintiffs' treating and prescribing physicians are presumably located outside of New Jersey and beyond this Court's subpoena power.

However, the parties have discussed, and Plaintiffs' March 10, 2017 letter to the Court advised the Court that they may be willing to voluntarily dismiss the cases lacking personal jurisdiction which would obviate the need for motion practice.

Defendants generally propose a case management and discovery plan in which the initial phase of the litigation is limited to jurisdictional and venue motions, if necessary, pleadings practice, product identification and proof of injury, causation discovery of Defendants, fact discovery of some of the Plaintiffs' claims, and motion practice regarding general causation. Defendants seek a case management mechanism that puts Plaintiffs to some level of proof early in the proceedings, prior to collecting *all* medical records, deposing plaintiffs and healthcare providers, and retaining and deposing extraneous experts for cases that may be meritless. Such an Order will be particularly necessary in this case where the evidence regarding the identity of the product at issue, the circumstances regarding each Plaintiff's alleged ingestion of that product, and evidence demonstrating a causal link between that ingestion and the injuries alleged are basic components of a plaintiff's *prima facie* case.

Defendants anticipate that many of the Plaintiffs will be unable to meet these benchmarks and early discovery of these basic issues will not only assist in reaching the issues as to whether any cases have merit, but in ensuring that the parties do not waste money and resources collecting medical records and litigating those cases which are meritless. Given the length of time PPIs have been on the market, product identification will be a key and potentially dispositive initial issue as AstraZeneca is the only named defendant in the captioned cases. Any Plaintiff surviving (or not subject to) jurisdictional/venue motion practice (if necessary) should be required to initially provide pharmacy record(s) demonstrating proof of ingestion, and medical record(s) demonstrating confirmed *subsequent* diagnosis of injury. Those unable to provide this basic *prima facie* proof should be subject to prompt dismissal before the parties embark upon collection of all medical records and the taking of depositions for that plaintiff. If, in fact, a plaintiff cannot come forward with the basic evidence linking his or her alleged injuries to a defendant's product, causation is not possible and litigation as to other issues of liability and damages would be unnecessary and a waste of the Court's and parties' resources.

Furthermore, each Plaintiff must show that AstraZeneca's alleged failure to warn of alleged adverse effects (generally, renal injuries) was the cause-in-fact of his or her alleged injuries. Plaintiffs here allege a series of different acute and chronic kidney conditions ranging from acute kidney injury ("AKI") to chronic kidney failure ("CKD"). Significantly, AstraZeneca has warned physicians of the possibility of acute interstitial nephritis ("AIN"), a type of AKI, as associated with Nexium® use, since 2006 when interstitial nephritis was added to the Nexium® physician prescribing information. However, as described by the Food and Drug Administration, AIN associated with PPI use is "thought to be an idiosyncratic, hypersensitivity reaction."[4] Moreover, nearly all

4 Letter from Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research, Dep't of Health & Human Services to Sidney M. Wolfe, M.D., Public Citizen, et al. (Oct. 31, 2014).

medications can cause this rare effect.[5] The most common drug-induced causes of AIN are antibiotics and non-steroidal anti-inflammatory drugs (NSAIDs).[6] Accordingly, plaintiffs alleging AKI[7] associated with Nexium® use would need to overcome the adequacy of the 2006 warning, as well as the fact that AIN is an idiosyncratic reaction, and show that their particular AIN was caused by Nexium® use.[8]

To the extent plaintiffs claim that Nexium® use caused chronic kidney function decline, i.e. CKD, the science supporting such a claim is immature and unreliable. Regardless, CKD is a prevalent, multi-factorial disease which affects more than 10 percent of the U.S. population.[9] Its generally-accepted, known causes include hypertension and diabetes among many others.[10] Thus, plaintiffs alleging CKD must overcome the paucity of scientific evidence to establish a duty to warn, as well as to prove general causation. Moreover, each plaintiff will need to demonstrate that his or her disease was drug-induced rather than due to other chronic health condition(s).

Thus, AstraZeneca contends that Plaintiffs will not be able to demonstrate general causation, which would be dispositive of all the cases, or specific causation on an individual Plaintiff basis, regardless of the claimed renal injury. There are numerous known causes for increased risk of the renal injuries alleged, and each Plaintiff will have to rule out these other causes before they could ever demonstrate that Nexium® use was the cause-in-fact of Plaintiff's injury, a burden AstraZeneca contends they will be unable to meet. Summary judgment should be granted in favor of Defendants for any plaintiff unable to show an issue of fact with regard to whether PPIs can cause an injury of the type he or she alleges (general causation).

Additionally, AstraZeneca asserts that Plaintiffs will be unable to establish design defect, manufacturing defect, failure to warn, and/or breach of express warranty under the relevant Product Liability Acts because AstraZeneca's warnings were adequate and/or any lack of warning was not the proximate cause of each Plaintiff's alleged injury.

Defendant also contend that Plaintiffs' claims are insufficiently pled and barred by New Jersey statutory and other applicable law including, but not limited to, statute of

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5 Manuel Praga, et al. *Clinical manifestations and diagnosis of acute interstitial nephritis*, UpToDate, topic last updated Oct. 12, 2016, http://www.uptodate.com/contents/clinical-mainifestions-and-diagnosis-of-acute-interstitial-nephritis (last visited Feb. 23, 2017).

6 *Id.*

7 In addition, all plaintiffs allege that AIN "if left untreated" can lead to CKD. *See, e.g. Savage Compl.* at ¶34. Thus, Plaintiffs appear to concede that their initial alleged injury was AIN and, accordingly, the warning's accuracy and the idiosyncratic nature of AIN would serve as hurdles for this claim as well.

8 Significantly, AIN is not only caused by nearly all medications, but also by chronic autoimmune diseases and many types of infections. Praga, et al., *supra* n.3. Additionally, while AIN can by primary, it can also be secondary to other renal conditions. *Id.*

9 Centers for Disease Control and Prevention (CDC). National Chronic Kidney Disease Fact Sheet: General information and National Estimates of Chronic Kidney Disease in the United States, 2014. Atlanta, GA: US Department of Health and Human Services, Centers for Disease Control and Prevention; 2014.

10 *Id.*

limitations, the learned intermediary doctrine, the doctrine of comparative fault, the relevant portions of the governing Products Liability Acts and the other defenses set forth in AstraZeneca's Answers, which will be raised at the appropriate time.

Because this action involves product liability claims involving prescription pharmaceutical products, extensive medical and scientific discovery will be needed. AstraZeneca's causation-related documents for Nexium® are voluminous; consisting of millions of pages of documents related to causation, medical, scientific, and regulatory issues alone. Consequently, given the particular circumstances of this case, Defendants request that the Court establish a case management plan that incorporates various stages and benchmarks to ensure the most efficient management and progression of the litigation.

Plaintiffs' proposed plan is neither realistic, nor efficient, for governance of these complex, pharmaceutical cases, particularly with respect to their suggestion of litigating the claims of only bellwether plaintiffs of their choosing. Defendants are prepared to discuss in more detail at the Initial Status Conference and respectfully request permission to brief the issues if the Court is inclined to adopt Plaintiffs' proposed plan.

3. No settlement discussions have taken place. No demand has been issued to date.

4. The parties have conferred pursuant to Fed. R. Civ. P. 26(f).

5. The parties have exchanged Initial Disclosures as required by Fed. R. Civ. P. 26(a)(1).

6. The parties have exchanged and are conferring on an electronic discovery order, preservation order, and a protective order to govern the captioned cases pursuant to L. Civ. R. 26.1(d). The parties will continue to confer after the initial Status Conference to ensure compliance with L. Civ. R. 26.1(d) and submit to the Court for entry at an appropriate time.

7. Proposed ALTERNATIVE discovery plans:

The parties anticipate both fact and expert discovery on the liability and damages issues described above. Thus far, the parties have been unable to agree on a discovery plan and schedule. While the parties will continue to confer in hopes of finding areas of agreement, their competing proposals are as follows:

Plaintiffs' Proposed Discovery Schedule

As the Court is aware, Defendants opposed Plaintiffs' petition for an MDL in connection with these cases. Plaintiffs therefore wish to move forward as expeditiously as possible on all issues in the cases before Your Honor, consistent with the discovery available to Plaintiffs under the federal rules. We believe it is necessary to move quickly for the benefit of our clients and that the discovery obtained in these initial cases will be of benefit to other NJ plaintiffs alleging similar claims against Defendants.

1. In each currently filed case, each Plaintiff shall serve Requests for Production and Interrogatories on or before March 24, 2017.

2. Defendants shall begin a rolling production of electronically stored information (ESI) and documents commencing on or before April 24, 2017.

3. Plaintiffs shall provide Defendants with topics for initial 30(b)(6) depositions (e.g., corporate organization, document preservation and retention) on or before March 10, 2017 and these initial depositions shall be completed on or before April 28, 2017.

4. In each currently filed case, Defendants shall serve Requests for Production and Interrogatories on Plaintiffs on or before May 24, 2017.

5. On or before August 3, 2017, two cases, in which Plaintiffs Responses to Interrogatories and Requests for Production have been served on or before July 10, 2017, will be selected by the Plaintiffs for the first two trials in this District. The cases selected shall only have AstraZeneca and/or Proctor and Gamble as the only defendants.

6. On or before December 15, 2017, Defendants must certify a good-faith belief that all ESI and documents requested on or before the Plaintiffs and/or ordered by this Court to be produced have in fact been produced.

7. Any depositions that the parties believe are necessary prior to expert reports being served shall be completed on or before February 28, 2018.

8. Plaintiffs' Rule 26(a)(2) expert reports for all experts for the first two trials shall be served on or before March 23, 2018.

9. Defendants' Rule 26(a)(2) expert reports for all experts for the first two trials shall be served on or before April 23, 2018.

10. On or before April 30, 2018, the Plaintiffs will advise the Defendants as to which of the two previously identified cases they will request that the Court set for the first trial setting and such request to the Court shall be made on May 7, 2018.

11. All expert depositions in both of the identified cases shall take place from April 16, 2018 through June 21, 2018.

12. *Daubert* and all dispositive motions shall be filed on or before June 30, 2018.

13. Oppositions to *Daubert* and any dispositive motions shall be filed on August 9, 2018.

Jury Selection in the first trial shall be November 3, 2018. An Order will be later issued with deadlines for pre-trial exchanges, motions in limine, arguments, pre-trial conferences and the second trial date.

AstraZeneca's Proposed Discovery Schedule

(a) Defendants propose that discovery is needed on the following subjects:

AstraZeneca anticipates both fact and expert discovery on the liability and damages issues in the captioned cases. AstraZeneca proposes initial discovery related to:

- AstraZeneca suggests meeting and conferring about categories for any production by AstraZeneca in lieu of formal discovery requests. Defendants will agree to commence production of documents and information related to product development, clinical/testing, labeling, regulatory history, safety, adverse event reporting, and medical literature ("causation-related documents") after execution and entry by the Court of a mutually agreeable Protective Order governing the confidentiality and production of Documents and an electronically stored information ("ESI") Agreement.

- AstraZeneca suggests that production of prima facie pharmacy records confirming use of Nexium and medical records confirming diagnosis of the injury alleged in the Complaint should occur at the outset of the litigation.

- AstraZeneca suggests use of a Plaintiff Fact Sheet for each Plaintiff and can meet and confer with counsel on the appropriate form.

(b) Discovery should be conducted in phases:

If needed, a proposed briefing schedule with respect to AstraZeneca's jurisdictional, venue and other pleadings practice initial motions is set forth below.

Any Plaintiff surviving (or not subject to) jurisdictional/venue motion practice should be required to provide, within the dates suggested below, pharmacy record(s) demonstrating proof of ingestion, and medical record(s) demonstrating confirmed *subsequent* diagnosis

of injury. Those unable to provide this basic *prima facie* proof should be subject to prompt dismissal.

Failure by Plaintiffs to prove medical causation would be dispositive of each entire action and litigation as to other issues of liability and damages would be unnecessary and a waste of resources. Early resolution of this basic issue promotes judicial economy in the litigation of complex products liability cases such as this. AstraZeneca suggests it would save substantial time and money of the parties and the Court to deviate from a standard scheduling order to front-load the issue of medical causation. Therefore, AstraZeneca proposes a case management plan in which the initial phase of the litigation is limited to causation-related discovery of AstraZeneca, certain fact discovery of Plaintiffs, designation and discovery of Plaintiffs' medical causation-related experts, and motion practice regarding cause-in-fact causation. At the conclusion of Phase One, summary judgment in favor of AstraZeneca is appropriate if Plaintiffs are unable to show an issue of fact with regard to cause-in-fact, *i.e.* whether (1) Nexium® can cause the types of injuries alleged by Plaintiffs (general causation) or (2) Nexium® caused each specific Plaintiff's alleged injuries (specific causation). Alternatively, if any Plaintiffs are able to demonstrate an issue of fact on causation, the parties will meet and confer regarding the timeliness of a settlement conference and/or propose to the Court a Phase Two Scheduling Order to govern the remaining issues through trial.

After execution by the parties and entry by the Court of a mutually agreeable Protective Order and ESI Agreement, AstraZeneca will begin a rolling production of millions of pages related to causation, medical, scientific and regulatory issues. Obviously, Plaintiffs will require sufficient time to review this large production. AstraZeneca recommends production of causation-related documents only during this phase because, in addition to the fact that AstraZeneca has already spent a substantial amount of money on document collection, it is AstraZeneca's position that non-causation sources (*e.g.* promotional/marketing/sales materials) are (1) wholly irrelevant to an analysis of medical causation; and (2) generally irrelevant to the issues in this litigation. In the interest of time and judicial economy, it is rational to postpone any such discovery until after the dispositive issue of causation is resolved. If Plaintiffs are able to establish general and specific causation, the parties and the Court can then discuss what, if any, non-causation documents should be produced. AstraZeneca will continue to meet and confer with Plaintiffs on these issues and the parties should agree to meet and confer in advance of any discovery-related motion practice in this case.

AstraZeneca will begin production of its causation-related documents within 30 days of entry of the Protective Order and ESI Agreement. AstraZeneca will continue to negotiate with Plaintiffs' counsel as to any reasonable request for additional documents and/or sources, and will update the production as needed within the deadlines proposed below.

Contemporaneous with AstraZeneca's document production, the parties will conduct discovery of Plaintiffs. This includes verified responses to an agreed or Court-ordered

Plaintiff Fact Sheet, production/collection of relevant records, and possible deposition discovery of Plaintiffs and any health care providers and/or witnesses deemed to possess information reasonably likely to lead to the discovery of admissible evidence related to medical causation issues. While it may be necessary to gain an understanding of Plaintiffs' alleged damages with an eye towards potential settlement discussions, issue is irrelevant to an analysis of medical causation and thus will be largely deferred until Phase Two. If Plaintiffs are able to establish general and specific causation, discovery of these issues will be addressed in a subsequent (Phase Two) scheduling order.

The deadlines proposed below govern Plaintiffs' designation of causation expert witness(es) and provision of each report, as well as discovery of the designated experts and timing of any summary judgment motion by AstraZeneca addressing causation (and/or any motions to limit or exclude causation experts). AstraZeneca proposes that after briefing is complete on these motions, the Court engage in Daubert and causation hearings as appropriate.

AstraZeneca believes this proposal to front-load causation allows ample time for completion of medical causation-related discovery, culminating in resolution of these issues without expending resources on issues irrelevant to Phase One. If upon motion practice, the Court determines that Plaintiffs are unable to show an issue of fact with regard to causation, judgment in favor of AstraZeneca would be appropriate. Alternatively, if AstraZeneca's motions are denied or AstraZeneca deems causation motion practice unwarranted, AstraZeneca proposes that the parties meet and confer regarding the timeliness of a settlement conference and propose to the Court a Phase Two Scheduling Order to govern the remaining issues through trial. AstraZeneca requests that any case management order recognize that, by filing a causation summary judgment motion in Phase One, Defendants do not waive the ability to file a separate summary judgment motion, in Phase Two, on other issues relating to liability and/or damages.

(c) Proposed schedule: [**Note to Court: AstraZeneca has intentionally not provided specific dates for some of the deadlines, desiring first to discuss the overall approach with the Court and counsel at the March 20, 2017 Status Conference to agree upon an acceptable timeframe.]**

1. Fed. R. Civ. P. 26 Disclosures: **March 24, 2017**

2. Briefing Schedule on AstraZeneca's initial dispositive, jurisdictional and venue motions for Non-Resident Plaintiffs (if necessary):

   AstraZeneca's opening briefs: _____

   Plaintiffs' Responses: _____

AstraZeneca's Replies: _____

3. Resident Plaintiffs to provide 1) pharmacy records demonstrating proof of AstraZeneca product alleged in Complaint and 2) medical record demonstrating diagnosis of injury alleged in Complaint *subsequent* to use of AstraZeneca product: _____

4. For any Resident Plaintiff who is unable to provide the initial prima facie records set forth in Section 7. (c) 3 above, AstraZeneca will advise Plaintiff's counsel in writing of any deficiencies within **10 days**. The parties will have **7 days** to meet/confer regarding the deficiencies. If Plaintiff is unable to cure the deficiencies, Plaintiff's counsel shall dismiss the case without prejudice. If Plaintiff does not dismiss the offending case, AstraZeneca can raise the matter with the Court for dismissal under this provision.

5. Deadline to file Agreed Plaintiff Fact Sheet (or, if the parties cannot agree, to submit competing proposals):_____

6. Resident Plaintiffs must serve a completed, signed Plaintiff Fact Sheet within **45 days** of the Court's entry of an approved Plaintiff Fact Sheet.

7. Should the Court deny AstraZeneca's initial dispositive, jurisdictional and venue motions with respect to the Non-Resident Plaintiffs (if such motion practice is necessary), Non-resident Plaintiffs must comply with the provisions of Section 7. (c) 3, 4 and 6 **within 45 days** of the Court's denial. If the Court has not yet entered an approved Plaintiff Fact Sheet, Plaintiffs must comply with Section 7. (c) 3 and 4, but shall otherwise have **45 days** after the Court's entry of an approved Plaintiff Fact Sheet to serve the completed, signed Plaintiff Fact Sheet upon counsel for AstraZeneca.

8. Within **30 days** of the entry of a Protective Order/ESI Agreement, AstraZeneca shall begin a rolling production of safety, regulatory and causation-related documents.

9. Deadline for Plaintiffs to meet/confer with AstraZeneca counsel on any supplemental causation-related productions:_____

10. Close of causation-related discovery of AstraZeneca:_____

11. Plaintiffs must designate cause-in-fact causation experts, if any, and provide expert reports for each as governed by FED.R.CIV.P. 26: _____

12. Deadline for AstraZeneca to file summary judgment motion addressing causation (and/or motions to limit or exclude Plaintiffs' causation experts, if any):_____

13. If AstraZeneca is unsuccessful on summary judgment with respect to any of the Plaintiffs, the parties will meet and confer and provide a phase two scheduling order within **30 days** of the Court's order(s) on summary judgment.

Report dated: March 15, 2017

Respectfully Submitted,

Attorneys for Various Plaintiffs

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